JUN 3 0 2000

K001688

June 28, 2000

Subject: 510(k) Summary TuffSat 3000 Pulse Oximeter (K001688)
Proprietary: Datex-Ohmeda TuffSat 3000 Pulse Oximeter
Common: Oximeter
Classification: Oximeter Class II – 21 CFR 870.2700 – 74 DQA

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA of 1990 and 1992.

The Datex-Ohmeda TuffSat 3000 Pulse Oximeter (K001688) is substantially equivalent to the following currently marketed device:

- Datex-Ohmeda TuffSat 3000 Pulse Oximeter (K993512)

The Datex-Ohmeda TuffSat 3000 Pulse Oximeter is a non-invasive, spot-check, oxygen saturation and pulse rate monitor. It operates only on battery power using existing Datex-Ohmeda disposable and reusable finger and ear sensors labeled for patients ranging from neonates to adults.

There is no change in the fundamental scientific technology nor the intended use of the device from that of the predicate device.

The Datex-Ohmeda TuffSat 3000 Pulse Oximeter was designed to comply with applicable portions of the following standards:

IEC 601-1	Medical Electrical Equipment – General Requirements for Safety
IEC 601-1-1	Safety Requirements for Medical Electrical Systems
IEC 601-1-2	Electromagnetic compatibility – Requirements and tests
CAN/CSA C22.2 #601	Medical Electrical Equipment – General Requirements for Safety
UL 2601-1	Medical Electrical Equipment – General Requirements for Safety
ISO 9919	Pulse Oximeters for Medical Use – Requirements
EN 865	Pulse Oximeters – Particular Requirements
ASTM 1415	Standard Specification for Pulse Oximeters
EN 1441	Medical Devices
IEC 601-1-4	Programmable Electrical Medical Systems

The Datex-Ohmeda TuffSat 3000 Pulse Oximeters K001688 and K993512 are substantially equivalent in design concepts, technologies and materials. The Datex-Ohmeda TuffSat 3000 Pulse Oximeter was validated through rigorous testing performed both in-house and at Nationally Recognized Testing Lab This testing supports the compliance of the Datex-Ohmeda TuffSat 3000 Pulse Oximeter to the above mentioned standards.

Additionally, the software for the Datex-Ohmeda TuffSat 3000 Pulse Oximeter was developed following a robust software development process and was specified and validated by Datex-Ohmeda.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2000

Mr. Dale Thanig
Datex-Ohmeda, Inc.
1315 West Century Drive
Louisville, CO 80027-9560

Re: K001688
TuffSat 3000 Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: May 31, 2000
Received: June 2, 2000

Dear Mr. Thanig:

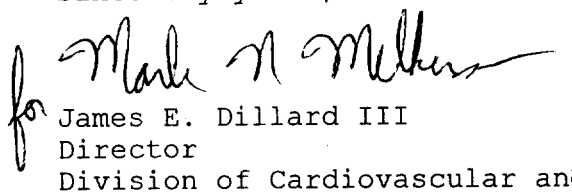
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K001688

Device Name: Datex-Ohmeda TuffSat 3000 Pulse Oximeter

Indications for Use:

The Datex-Ohmeda TuffSat 3000 Pulse Oximeter is a non-invasive, spot-check, oxygen saturation and pulse rate monitor. It operates only on battery power using existing Datex-Ohmeda disposable and reusable finger and ear sensors labeled for patients ranging from neonates to adults.

US federal and Canadian laws restrict the sale of this device by or on the order of a licensed medical practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510K Number: K001688

Prescription Use ✓ OR Over-The-Counter _____
(Per 21CFR801.109)